
NEW
Now in non-prescription strength
Prevents:
Heartburn,
Acid Indigestion
& Sour Stomach.
AXID AR
Acid Reducer
Nizatidine Tablets 75 mg
12 TABLETS (12 DOSES)
AXID AR
Acid Reducer
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12 TABLETS (12 DOSES)
CLOSE TIGHTLY
WHILE PUSHING DOWN TURN
60 NDC 0002-3144-60
PULVULES® No. 3144
Lilly
Rx Pak
AXID®
NIZATIDINE
CAPSULES, USP
150 mg
AXID AR
AXID AR
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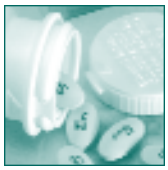
AXID AR



Now Available *Without* a pRescription Rx

For those who yearn to break their cigarette addiction but don't fancy a trip to the doctor's office, the ability to get the nicotine patch without a physician's prescription may be just what the doctor ordered.

Until a few years ago, the nicotine patch was available by prescription (Rx) only. In July 1996, the Food and Drug Administration approved the "switch" of the Nicotrol patch to over-the-counter (OTC) status, following on the heels of a February 1996 switch of another smoking cessation aid containing nicotine, Nicorette gum. Then, on Aug. 2, 1996, FDA approved the switch of a second nicotine patch, Nicoderm CQ.

On the right is the prescription-strength Axid and on the left the OTC product. Axid and three other heartburn medications—Pepcid, Tagamet and Zantac—were switched to OTC status. To enable consumers to treat their own heartburn safely, FDA approved the over-the-counter drugs with easy-to-understand labeling and at a lower dosage than the prescription versions.

Over-the-counter switches provide increased access to effective drugs.

The "patch" and Nicorette gum join more than 600 other OTC drugs that, according to the Nonprescription Drug Manufacturers Association, would have required a prescription only 20 years ago. The 600-plus products are now available without a prescription because FDA, in cooperation with panels of outside experts, determined they could be used safely and effectively without a doctor's supervision.

In the last year and a half alone, FDA has given OTC approval to drugs with such household names as Children's Advil and Children's Motrin (ibuprofen), Orudis KT (ketoprofen) and Actron (naproxen sodium), for pain relief and fever reduction; Femstat 3 (butoconazole nitrate), for vaginal yeast infection; Pepcid AC (famotidine), Tagamet HB (cimetidine), Zantac 75 (ranitidine hydrochloride), and Axid AR (nizatidine), for heartburn; and Rogaine (minoxidil), for hair growth.

Over-the-counter switches provide increased access to effective drugs. Eighty-five percent of Americans feel it is important to have OTC medications available to relieve minor medical problems, according to a 1992 Heller Research Group study, "Self-Medication in the '90s: Practices and Perceptions."

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— Debra Bowen, M.D., FDA

Director of Over-the-Counter Drug Products Division

Bowen, M.D., director of FDA's division of over-the-counter drug products. "It's part of our mission to keep up with the consumer's wish to be more involved."

Switches have a huge impact on the healthcare economy. The greater availability of medicines over the counter saves approximately $20 billion each year, according to the *1995 Physicians' Desk Reference for Nonprescription Drugs*, a book of drug information published annually by Medical Economics in cooperation with drug manufacturers. The $20 billion takes into account prescription costs, doctor visits, lost time from work, insurance costs, and travel.

The Switch Process

The original Federal Food, Drug, and Cosmetic Act of 1938 made no clear-cut distinction between Rx and OTC drugs. The 1951 Durham-Humphrey amendments to the act set up specific standards for classification.

The amendment requires that drugs that cannot be used safely without professional supervision be dispensed only by prescription. Such drugs may be deemed unsafe for nonprescription use because they are habit-forming or toxic, have too great a potential for harmful effects, or are for medical conditions that can't be readily self-diagnosed.

All other drugs can be sold OTC. A drug must be made available without a prescription if, by following the labeling, consumers can use it safely and effectively without professional guidance.

Some drugs are approved initially as OTC drugs. More often, though, medications are first approved Rx and later switched. "While a product is available by prescription, we can learn about the drug's safety profile in a much more controlled environment," Bowen says.

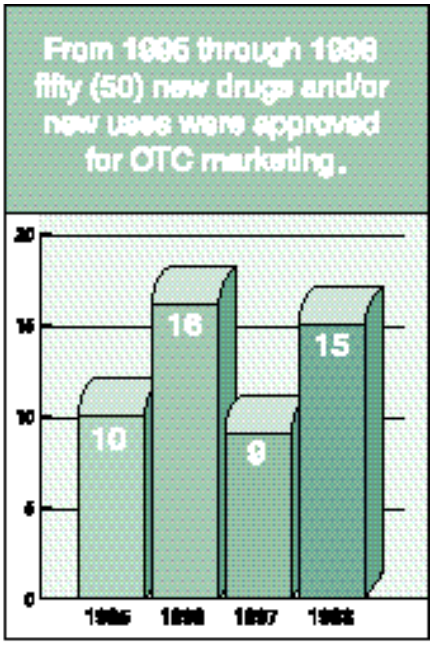
Drugs are commonly switched one of two ways: under the "OTC drug review," or by a manufacturer's submission of additional information to the original drug application.

The OTC drug review is an ongoing public process that allows communication through rulemakings and publications in the *Federal Register*, uses public meetings of nongovernment experts, and incorporates the agency's scientific opinion to establish the general recognition of safety and efficacy of OTC drugs that were in the marketplace prior to a certain date in the 1970s. Some of the expert review panels also reviewed prescription ingredients to recommend whether these ingredients were appropriate for certain OTC uses and for OTC marketing.

The second common path to OTC approval is submission of data to FDA (almost always by a manufacturer) showing the drug is appropriate for self-administration. Often, the submission includes studies showing that the product's labeling can be read, understood, and followed by the consumer without the guidance of a healthcare provider. FDA reviews the new data, along with any information known about the drug from its prescription use.

Some new drug applications for OTC use are presented to a joint advisory committee made up of members of the agency's Nonprescription Drugs Advisory Committee and another advisory committee with expertise in the type of drug being considered. For example, because Rogaine is for conditions of the hair and scalp, representatives of the Dermatologic Drugs Advisory Committee participated in this joint advisory committee meeting.

While not bound by the advisory committee's counsel, FDA frequently follows its recommendation.



Benefit vs. Risk Comparison

When considering an Rx-to-OTC switch, the key question for FDA is whether the drug can benefit consumers without endangering their safety.

No drug is absolutely safe. There are risks associated with every medication, so FDA assessess both the benefit and risk to determine whether it is appropriate for consumers to self-medicate with a drug for a certain use.

On the safety side, the agency looks at the drug's toxicity—its potential for poisonous effects—when the drug is used according to its labeled directions. The agency also determines whether the drug's side effects are acceptable given the benefit that the drug will provide. Finally, the agency evaluates the drug's potential for misuse or abuse.

While misuse by some consumers is inevitable—some people may overmedicate on the mistaken assumption that more is better—the Heller study showed that consumers appreciate the risks of taking any drug. Ninety percent of those surveyed said medications should only be used when absolutely necessary. Seventy percent said they prefer to fight symptoms without any medication.

FDA weighs a drug's safety against its benefit to consumers.The agency considers whether consumers will be able to understand and follow label directions, whether they can recognize their symptoms or condition themselves, and whether a medical examination or practitioner-prescribed laboratory tests are required for specific diagnoses or for the continued safe use of a drug.

No easy risk vs. benefit formula exists. FDA does a case-by-case review of each drug along with its intended use. In the past few years, the agency considered OTC switch applications for two very different drugs—Rogaine, for hair regrowth, and the nicotine patch, as an aid to smoking cessation. Each raised unique issues, yet the risk vs. benefit comparison led FDA to the same conclusions in the two assessments—over-the-counter status is appropriate.

Some people may overmedicate on the mistaken assumption that more is better.

Concerns about side effects can sometimes be managed by approving OTC drugs at lower doses than their prescription counterparts. The drugs must still be effective for the short-term symptoms for which they're intended.

The issue of whether a condition can be self-diagnosed was a central one for the Rogaine advisory committee. Most OTC drugs are intended for treatment of symptoms that can be easily recognized, like headache or upset stomach. Others, though, are intended to treat diseases like asthma or vaginal fungal infections, which cannot be self-diagnosed.

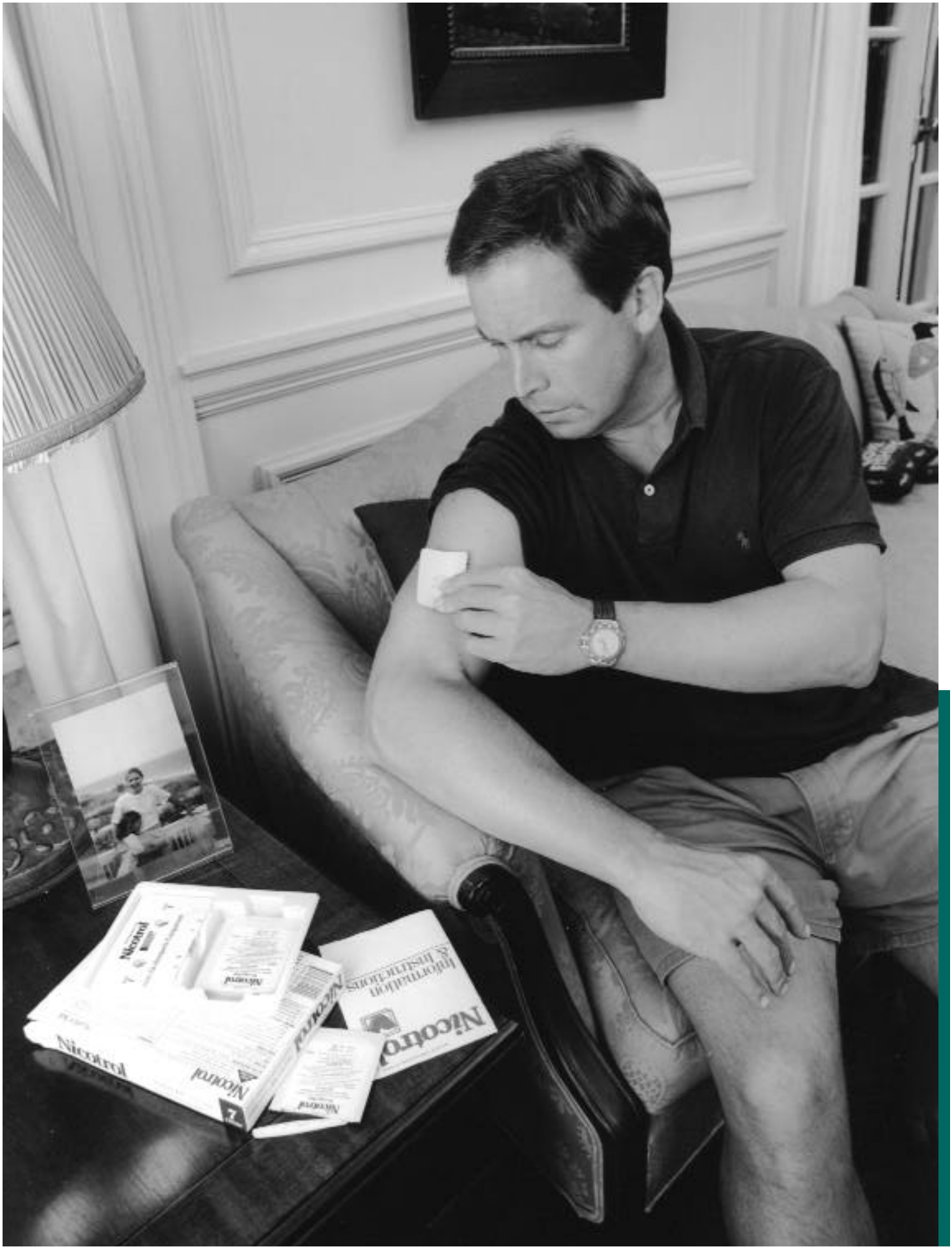
Consumer-Friendly Labeling

Labeling is an influential element in deciding whether the risk of using the OTC drug is acceptable. The decision about a drug's safety for OTC use cannot be made in a vacuum, by looking only at the drug ingredients. Every drug, used improperly, can cause adverse reactions. Even appropriate use can lead to side effects (e.g., antihistamine use may cause drowsiness). And some drugs can be dangerously unsafe or ineffective if taken while a person is using certain other drugs.

Labeling can alert consumers to such potential problems. Labeling of all drugs must be clear and truthful. For OTC drugs, the intended uses, directions, and warnings have to be written so consumers, including individuals with low reading comprehension, can understand them.

FDA is working with the pharmaceutical industry to increase the readability of OTC labels by making the language more consumer-friendly and standardizing the format, including where important information is placed.

In some cases, Bowen says, consumers can get more information in the OTC labeling than they would get from their doctors. "For the nicotine patch, we developed a package—a package containing not only a drug that relieves withdrawal symptoms, but also behavioral modification information. The package provides an element of support, which studies showed some people weren't getting from their doctors, by telling them when they'll most likely feel the urge to smoke, what they can do in


Nicotrol
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place of smoking, and where they can go for support."

A Popular Alternative

Nicorette gum magazine ads announce, "Nicorette Gum Is Now Available Full Strength Without A Prescription. Hallelujah!" "Hallelujah" may be the victory cry for those who, with the aid of OTC nicotine gum, were able to beat the cravings. But consumers aren't the only ones with something to gain from Rx-to-OTC switches.

Some manufacturers are exclaiming "Hallelujah" as well, over profits gained from direct access to millions of consumers. Pepcid AC for heartburn, for example, had sales topping $200 million in the first year after the product's April 1995 switch approval, making it the most profitable switch to date.

Today's emphasis on self-managed care fuels the popularity of nonprescription drugs. But OTC products are intended to supplement the medical options of the consumer, not substitute for a prescriber's medical knowledge. If a health problem persists or worsens while you are using an OTC drug, consult a healthcare provider.

In some cases, Bowen says, consumers can get more information in the OTC labeling than they would get from their doctors.

"People must be in a partnership with their healthcare providers for optimal health," Bowen says. "Many situations aren't appropriate for self-treatment, and others may require professional guidance for self-treatment."

If you do choose OTC treatment, heed Bowen's warning: "Drugs aren't candy; they aren't risk-free. You have to follow the label and take appropriate responsibility for your own self-care."

9-0 Vote for OTC Nicotrol

Nicotrol was the first nicotine patch for smoking cessation approved by FDA.

It received an advisory committee's unanimous recommendation for a prescription-to-OTC switch on April 19, 1996. Worn for 16 hours a day, the patch reduces nicotine cravings by providing a constant, controlled flow of nicotine into the bloodstream.

The committee concluded that the benefits of this smoking cessation aid outweigh its risks, but only after considering manufacturer McNeil Consumer Products' proposed labeling and marketing plans, and the company's studies comparing quitting rates for OTC and prescription patches.

The company presented data showing that prescription and OTC patch users achieved similar quitting rates (19 percent of OTC users abstained in weeks 2 through 6, versus 16.6 percent of Rx users) and experienced no serious adverse reactions.

McNeil demonstrated that smokers understood the proposed labeling, including the warning not to smoke while using the patch and directions on how to apply and remove the patch. According to the company, more than 80 percent of consumers used the behavioral modification materials, including handbooks, an audiotape, and toll-free help line.

The committee was told that abuse was not expected to be a problem, especially for adults. The patches are not to be sold to minors and will not be distributed through vending machines. Advertising will be targeted to adults.

FDA agreed that the benefits of the patch—an increased chance for people to quit smoking—outweighed any slight risks, and approved the product for OTC sale July 3, 1996. The OTC patches became available in retail stores July 18, 1996.